PROTEIN TECHNOLOGIES INTERNATIONAL
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September 22, 1999

BY HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Proposed Rule; Health Claims, Soy Protein and Coronary Heart Disease; Docket No. 98P-0683

Dear Sir or Madam:

Protein Technologies Inc. (PTI) welcomes this opportunity to comment on the above-captioned rule relating to the appropriate methods and procedures for assessing compliance with the proposed health claim linking consumption of soy protein with reduced risk of coronary heart disease. PTI submitted extensive comments in support of the proposed claim on January 25, March 26 (providing supplemental scientific information), and April 10 (providing supplemental scientific information), 1999. As Petitioner, PTI was particularly pleased that the vast majority of comments overwhelmingly supported the proposed rule. PTI is the largest manufacturer of isolated soy protein (ISP) in the United States, supplying ISP to manufacturers of a wide range of value-added conventional food and dietary supplement products.

PTI submitted its petition seeking authorization of a soy protein/CHD health claim on May 4, 1998, and FDA published a proposed rule authorizing the claim only six months later. FDA's prompt action on the petition reflected its diligent work in evaluating the underlying scientific evidence. PTI applauds the agency's recognition of the tremendous health benefits of soy protein and looks forward to the publication of a final rule in the near future that will permit food manufacturers to communicate this important information to consumers.

In the above-captioned proposed rule, FDA advises that only one issue relating to the soy protein/CHD claim remains outstanding and that the agency will publish a final rule authorizing the claim after reviewing and considering the comments it receives. The remaining issue is the appropriate method for assessing

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compliance with the proposed requirement that foods bearing the health claim contain a specific minimum level of soy protein. As the agency and many commenters have recognized, no single validated analytical method exists that accurately measures the soy content of all foods. The problem arises due to the complexity of developing a single method appropriate for all different kinds of foods.

PTI agrees that FDA must have available to it an objective means of verifying the soy protein content of foods that bear the claim. At the same time, PTI shares FDA's view that the absence of a validated analytical method should in no way delay or affect publication of a final authorizing regulation. Accordingly, PTI welcomes FDA's proposal to establish a means of assessing compliance that does not rely on a validated analytical method. The proposal distinguishes between foods in which soy is the sole source of protein and those that contain other protein sources as well.

PTI endorses FDA's proposal to consider the amount of soy protein in foods that contain no source of protein other than soy as equivalent to their total protein content. The total protein value of these foods, as measured by the AOAC method described in 21 C.F.R. § 101.9(c)(7), accurately reflects their soy protein content. Accordingly, PTI supports adoption of this approach by FDA but urges the agency to reiterate, in the preamble to the upcoming final rule, that in those instances in which a food's total protein content is derived from soy, additional information, in the form of manufacturer records or otherwise, is not necessary to assess the product's compliance with the rule, and FDA will not require it.

With respect to those foods which contain sources of protein in addition to soy, PTI recognizes the principle behind FDA's view that a reliable, verifiable mechanism for ensuring compliance is necessary. PTI is concerned, however, that the language used to describe the mechanism FDA proposes, and perhaps even the mechanism itself, are imprecise and over broad.

It is well-established that the Federal Food, Drug, and Cosmetic Act (FFDCA) does not give FDA unfettered access to the records of food manufacturers. Neither § 704 nor § 701 confers this power upon the agency. In fact, FDA has acknowledged publicly that it lacks such broad records access authority. Any approach adopted by FDA for assessing compliance based on access to manufacturers' information, therefore, must reflect this limitation on the agency's authority. The final rule must describe carefully and accurately the limited circumstances in which FDA may verify compliance on the basis of manufacturer records and impose the least intrusive records access provision necessary.

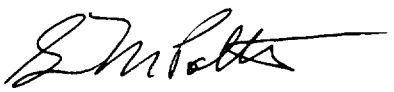
Specifically, PTI urges the agency to adopt a final rule that requires manufacturers to possess information to substantiate that a product contains a level of soy protein sufficient to qualify for the health claim and to make the information on which they are relying available to FDA on request. The language proposed by FDA with respect to the scope of information to which FDA would have access appears somewhat imprecise. It could be read to suggest that FDA would have authority to demand nutrient databases or analyses, recipes or formulations, purchase orders for ingredients or any other documents which the agency believed could be used to assess compliance.

Given the very limited provisions the FFDCA makes for access by FDA to records pertaining to foods, PTI believes it should be the manufacturer, not FDA, that identifies the records to which FDA would have access. This will ensure that FDA has access to information sufficient to allow it to assess compliance yet protect manufacturers from broad, unwarranted requests for documents for which FDA lacks legal authority. At the same time, a manufacturer who makes a soy health claim will be on notice that it must possess a reasonable, verifiable basis for the soy protein content where soy is not the only source of protein. By adopting the least burdensome means of verification, the agency ensures that its compliance function will not unnecessarily discourage companies from utilizing the health claim because of needlessly broad records access demands by FDA.

Finally, PTI supports FDA's stated intention to pursue development of an analytical method(s) for measuring the soy protein content of foods and would welcome the opportunity to work cooperatively with the agency in that effort. PTI also supports FDA's stated intention to amend the final soy protein/CHD health claim rule to incorporate validated analytical methods for assessing compliance as they become available.

Thank you for this opportunity to comment. PTI welcomes the agency's planned publication of the final soy protein/CHD health claim rule.

Sincerely,



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